

**MAY 17 2000**

K000932

## **510(k) Summary**

**Submitter:** Advanced Medical Products, Inc.  
6600 West Charleston Boulevard – Suite 118  
Las Vegas, Nevada 89102

**Contact Person:** Jason G. Landess, Esq.

**Date of 510(k) Summary Preparation:** March 18, 2000

**Name of Device:** Arachnophlebectomy Needle

**Predicate Devices:** Manual surgical instruments and lasers intended for use in cutting and destroying leg veins

### **Device Description and Intended Use:**

There are two sharp prongs at the tip of the needle. After penetrating the skin, the prongs are placed astride the proximal end of the spider vein. The spider vein is interrupted by rotating the needle about its long axis for one or two revolutions. This procedure is repeated several times proximately. The needle is then withdrawn. The procedure is repeated until the spider veins in the target area are treated. Pressure is applied until the bleeding stops. A dry sterile bandage is then applied. The spider veins disappear through absorption of the interrupted segments.

### **Brief Description of Non-Clinical Testing:**

The 510(k) submission includes information on the composition of the device handle and needle. The device is labeled as being sterile. Appropriate information regarding its sterilization is provided.

### **Brief Description of Clinical Testing:**

This device was invented by a surgeon for exclusive use in his practice of medicine. Photographic evidence of the treatment results is provided. Except for transient bruising, there have been no complications associated with this procedure.

### **Conclusions Drawn:**

The intended use of the Arachnophlebectomy Needle is similar to that of the cited predicate devices. Information is submitted to demonstrate that any differences in technological characteristics do not raise new issues of safety or effectiveness and that the Arachnophlebectomy Needle is at least as safe and effective as legally marketed devices used for the same intended purpose.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

**MAY 17 2000**

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Advanced Medical Products, Inc.  
c/o Mr. Charles H. Kyper  
Kyper & Associates  
11902 Simpson Road  
Clarksville, Maryland 21029

Re: K000932  
Trade Name: Arachnophlebotomy Needle  
Regulatory Class: I  
Product Code: GAH  
Dated: March 18, 2000  
Received: March 23, 2000

Dear Mr. Kyper:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Mr. Charles H. Kyper

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

*Danne R. Witten*



Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative  
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): K000932

Device Name: Arachnophlebectomy Needle

Indications For Use:

The Arachnophlebectomy Needle is a manual surgical instrument intended for use in destroying spider veins in the lower extremities of the body.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

Dennis R. Lockman  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K000932